REMS
Initial REMS Approval: 11/06/2012
Most Recent Modification: February/2015

NDA 203,214 XELJANZ® (TOFACITINIB)

PF PRISM C.V.
c/o Pfizer Netherlands, Rivium Westlaan 142
2909 LD Capelle aan den Ijssel

NETHERLANDS

Authorized U.S. Agent: Pfizer Inc, NY

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

GOAL

The goal of the XELJANZ REMS is to inform healthcare providers about the serious risks associated with XELJANZ treatment.

REMS ELEMENTS:

Communication Plan

Pfizer Inc will implement a communication plan to the following healthcare providers:

- Rheumatologists and rheumatology healthcare providers (including physician assistants and nurse practitioners) who are likely to prescribe XELJANZ,
- Infectious disease specialists who may be consulted about and treat serious infections including herpes zoster, tuberculosis, and other opportunistic infections,
- Family practitioners, general practitioners, and internal medicine specialists who may be consulted about and be involved in treating serious infections, decreases in neutrophil counts, decrease in lymphocyte counts, decreases in hemoglobin, and lipid elevations and hyperlipidemia,
- Emergency medicine specialists who may evaluate and treat serious infections including herpes zoster, and tuberculosis and other opportunistic infections in emergency care settings, and
- Pharmacists who will dispense XELJANZ.

Elements of the communication plan include the following:

1. A Dear Healthcare Provider Letter will be distributed twice annually for 3 years to rheumatologists and rheumatology healthcare providers (including physician assistants and nurse practitioners), infectious disease specialists, family practitioners, general practitioners, internal medicine specialists, and emergency medicine specialists through both traditional mailing and electronic mailing. The initial letter will be distributed within 60 days of product approval. The Dear Healthcare Provider letter is enclosed in Appendix A.

   The Prescribing Information and a copy of the Medication Guide will also be distributed in this communication.

2. A Dear Pharmacist letter will be distributed to pharmacists twice annually for 3 years through both traditional mailing and electronic mailing. The initial letter will be distributed within 60 days of product approval. The Dear Pharmacist Letter is enclosed in Appendix B.

3. Dissemination of information about the known and potential serious risks associated with XELJANZ will be made to healthcare providers through certain professional societies' scientific meetings and journals.

   - Display, for 2 years following product approval, as a panel/poster and distribution as printed material at major convention meetings of rheumatologists and other healthcare professionals specializing in rheumatology where the company has a sponsored booth (e.g., American College of Rheumatology, Congress of Clinical Rheumatology, and American Society of Health System Pharmacists annual meetings).

   - Quarterly, for 3 years following product approval, presentation as a printed information piece in *The Rheumatologist, Arthritis & Rheumatology, Arthritis Care & Research, Clinical Infectious Diseases, Annals of Emergency Medicine, American Family Physician, Annals of Internal Medicine, American Journal of Health-System Pharmacy, and Journal of the Academy of Managed Care Pharmacy*. The drafts of the important drug warning that will be printed in the aforementioned scientific journals are enclosed in Appendices C through Appendix G.

4. Pfizer will ensure that all materials listed in or appended to the XELJANZ REMS program will be available through the XELJANZ REMS program website www.XELJANZREMS.com. The XELJANZ REMS program website will exist for 3 years following approval of the REMS. The landing page for the XELJANZ REMS website is appended (see Appendix H).

Timetable for Submission of Assessments

Pfizer will submit REMS Assessments to the FDA at 18 months, by 3 years and 7 years from the date of approval of the REMS (11-06-2012). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered

by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Pfizer will submit each assessment so that it will be received by the FDA on or before the due date.

Appendix A: Dear HealthCare Provider Letter

IMPORTANT DRUG WARNING

Subject: Risk of serious infections, malignancies, decreases in peripheral lymphocyte counts, neutrophil counts, hemoglobin, and increases in lipid parameters in peripheral blood with XELJANZ® (tofacitinib)

Dear Healthcare Provider,

The purpose of this letter is to inform you of important safety information for XELJANZ® (tofacitinib citrate), an inhibitor of Janus kinases (JAKs) approved by the Food and Drug Administration (FDA) for adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). The recommended dose of XELJANZ is 5 mg twice daily.

The safety and efficacy of XELJANZ® for conditions other than RA have not yet been established.

FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for XELJANZ to ensure that the benefits of the drug outweigh the potential risks.

Limitations of Use
XELJANZ is not recommended to be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.

Patient Counseling
You must discuss the risks associated with XELJANZ therapy with patients and in applicable instances with their caregivers.

Serious Risks of XELJANZ® (tofacitinib)

Serious Infections

- Patients treated with XELJANZ are at increased risk for developing serious infections leading to hospitalization or death, including active tuberculosis (TB), invasive fungal infections, bacterial, viral and other infections due to opportunistic pathogens. Most patients

who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

- Avoid use of XELJANZ in patients with an active infection, including localized infections. If a serious infection develops, XELJANZ should be interrupted until the infection is controlled.

- Prior to initiating XELJANZ, a test for latent TB should be performed. If the test is positive, treatment for TB should be started prior to starting XELJANZ. All patients should be monitored for active TB during treatment, including patients who tested negative for latent TB prior to initiating therapy.

- Cases of viral reactivation were observed in clinical studies with XELJANZ. Screening for viral hepatitis should be performed in accordance with clinical guidelines before starting therapy with XELJANZ.

Malignancies and Lymphoproliferative Disorders

- Consider the risks and benefits of XELJANZ treatment prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing XELJANZ in patients who develop a malignancy. Lymphoma and other malignancies have been reported in patients treated with XELJANZ.

- In the seven controlled rheumatoid arthritis clinical studies, 11 solid cancers and one lymphoma were diagnosed in 3328 patients receiving XELJANZ with or without DMARD, compared to 0 solid cancers and 0 lymphomas in 809 patients in the placebo with or without DMARD group during the first 12 months of exposure. Lymphomas and solid cancers have also been observed in the long-term extension studies in rheumatoid arthritis patients treated with XELJANZ.

- In Phase 2B, controlled dose-ranging studies in de-novo renal transplant patients, all of whom received induction therapy with basiliximab, high dose corticosteroids, and mycophenolic acid products, Epstein Barr Virus-associated post-transplant lymphoproliferative disorder was observed in 5 out of 218 patients treated with XELJANZ (2.3%) compared to 0 out of 111 patients treated with cyclosporine.

- Non-melanoma skin cancers have been reported in patients treated with XELJANZ and identified as an adverse drug reaction. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

Important Information on Laboratory Abnormalities

- Lymphocytes, neutrophils, hemoglobin, and lipids should be monitored, as abnormalities in these parameters were associated with XELJANZ treatment in Phase 3 clinical trials.

Medication Guide
The Medication Guide contains information that can be used to facilitate discussions about the known and potential risks of therapy. A copy is enclosed. The XELJANZ Medication Guide must be provided to patients being treated with XELJANZ or to their caregiver at the time of first dose or if the Medication Guide is materially changed. Additional copies of the Medication Guide may be obtained from the XELJANZ REMS web site (www.XELJANZREMS.com) or by calling Pfizer at 1-800-438-1985.

Reporting Adverse Events
To report any adverse events with the use of XELJANZ, contact:

- Pfizer Safety at 1-800-438-1985
- MedWatch (FDA safety information and adverse event reporting program) at 1-800-332-1088 or online at www.fda.gov/medwatch/report.htm

This letter is not a comprehensive description of the risks associated with the use of XELJANZ. Please read the accompanying Prescribing Information, including **BOXED WARNING**, and Medication Guide for a complete description of these risks.

For more information, please call Pfizer Medical Information at 1-800-438-1985 or visit the XELJANZ REMS web site (www.XELJANZREMS.com).

Sincerely,

Chief Medical Officer
Pfizer

Enclosure

Appendix B: Dear Pharmacist Letter

IMPORTANT DRUG WARNING

Dear Pharmacist,

The purpose of this letter is to inform you of important safety information for XELJANZ® (tofacitinib citrate), an inhibitor of Janus kinases (JAKs) approved by the Food and Drug Administration (FDA) for adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). The recommended dose of XELJANZ is 5 mg twice daily.

The safety and efficacy of XELJANZ® for conditions other than RA have not yet been established.

FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for XELJANZ to ensure that the benefits of the drug outweigh the potential risks.

Limitations of Use
XELJANZ is not recommended to be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.

Serious Risks of XELJANZ® (tofacitinib)

Serious Infections

- Patients treated with XELJANZ are at increased risk for developing serious infections leading to hospitalization or death, including active tuberculosis (TB), invasive fungal infections, bacterial, viral and other infections due to opportunistic pathogens. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

- Avoid use of XELJANZ in patients with an active infection, including localized infections. If a serious infection develops, XELJANZ should be interrupted until the infection is controlled.

- Prior to initiating XELJANZ, a test for latent TB should be performed. If the test is positive, treatment for TB should be started prior to starting XELJANZ. All patients should be

monitored for active TB during treatment, including patients who tested negative for latent TB prior to initiating therapy.

- Cases of viral reactivation were observed in clinical studies with XELJANZ. Screening for viral hepatitis should be performed in accordance with clinical guidelines before starting therapy with XELJANZ.

Malignancies and Lymphoproliferative Disorders

- Consider the risks and benefits of XELJANZ treatment prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing XELJANZ in patients who develop a malignancy. Lymphoma and other malignancies have been reported in patients treated with XELJANZ.

- In the seven controlled rheumatoid arthritis clinical studies, 11 solid cancers and one lymphoma were diagnosed in 3328 patients receiving XELJANZ with or without DMARD, compared to 0 solid cancers and 0 lymphomas in 809 patients in the placebo with or without DMARD group during the first 12 months of exposure. Lymphomas and solid cancers have also been observed in the long-term extension studies in rheumatoid arthritis patients treated with XELJANZ.

- In Phase 2B, controlled dose-ranging studies in de-novo renal transplant patients, all of whom received induction therapy with basiliximab, high dose corticosteroids, and mycophenolic acid products, Epstein Barr Virus-associated post-transplant lymphoproliferative disorder was observed in 5 out of 218 patients treated with XELJANZ (2.3%) compared to 0 out of 111 patients treated with cyclosporine.

- Non-melanoma skin cancers have been reported in patients treated with XELJANZ and identified as an adverse drug reaction. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

Important Information on Laboratory Abnormalities

- Lymphocytes, neutrophils, hemoglobin, and lipids should be monitored, as abnormalities in these parameters were associated with XELJANZ treatment in Phase 3 clinical trials.

Medication Guide
The FDA requires that a copy of the enclosed XELJANZ Medication Guide be distributed to patients who receive XELJANZ or to their caregiver at the time of dispensing or if the Medication Guide is materially changed. Additional copies of the Medication Guide may be obtained from the XELJANZ REMS web site (www.XELJANZREMS.com) or by calling Pfizer at 1-800-438-1985.

Reporting Adverse Events
To report any adverse events with the use of XELJANZ, contact:
- Pfizer Safety at 1-800-438-1985

- MedWatch (FDA safety information and adverse event reporting program) at 1-800-332-1088 or online at www.fda.gov/medwatch/report.htm

This letter is not a comprehensive description of the risks associated with the use of XELJANZ. Please read the accompanying Prescribing Information, including **BOXED WARNING**, and Medication Guide for a complete description of these risks.

For more information, please call Pfizer Medical Information at 1-800-438-1985 or visit the XELJANZ REMS web site (www.XELJANZREMS.com).

Sincerely,

Chief Medical Officer
Pfizer

Enclosure

Appendix C: Journal Information Piece For Rheumatologists or Rheumatology Healthcare Providers (including physician assistants and nurse practitioners)

Important Drug Warning for Rheumatologists and Rheumatology Healthcare Providers (including physician assistants and nurse practitioners) about Risks and Potential Risks with XELJANZ

XELJANZ® (tofacitinib citrate) is an inhibitor of Janus kinases (JAKs) approved by the Food and Drug Administration (FDA) for adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). The recommended dose of XELJANZ is 5 mg twice daily.

The safety and efficacy of XELJANZ® for conditions other than RA have not yet been established.

Limitations of Use
XELJANZ is not recommended to be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.

Serious Risks of XELJANZ® (tofacitinib)
Serious Infections: Patients treated with XELJANZ are at increased risk for developing serious infections leading to hospitalization or death, including active tuberculosis (TB), invasive fungal infections, bacterial, viral and other infections due to opportunistic pathogens. Avoid use of XELJANZ in patients with an active infection, including localized infections. If a serious infection develops, XELJANZ should be interrupted until the infection is controlled.

Malignancies and Lymphoproliferative Disorders: Consider the risks and benefits of XELJANZ treatment prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing XELJANZ in patients who develop a malignancy. Lymphoma, solid cancers, and NMSC have been reported in patients treated with XELJANZ. NMSC has been identified as an adverse drug reaction.

Laboratory Abnormalities: Lymphocytes, neutrophils, hemoglobin, and lipids should be monitored, as abnormalities in these parameters were associated with XELJANZ treatment in Phase 3 clinical trials. Please see the full Prescribing Information for more information.

Reporting Adverse Events
To report any adverse events with the use of XELJANZ, contact:

- Pfizer Safety at 1-800-438-1985
- MedWatch (FDA safety information and adverse event reporting program) at 1-800-332-1088 or online at www.fda.gov/medwatch/report.htm

This is not a comprehensive representation of the potential risks associated with use of XELJANZ. For a complete description of these potential risks, please visit the XELJANZ REMS web site (www.XELJANZREMS.com) for Prescribing Information and Medication Guide.

Appendix D: Journal Information Piece For Infectious Disease Specialists

Important Drug Warning for Infectious Disease Specialists about Risks and Potential Risks with XELJANZ

XELJANZ® (tofacitinib citrate) is an inhibitor of Janus kinases (JAKs) approved by the Food and Drug Administration (FDA) for adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). The recommended dose of XELJANZ is 5 mg twice daily.

The safety and efficacy of XELJANZ® for conditions other than RA have not yet been established.

Limitations of Use
XELJANZ is not recommended to be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.

Serious Risks of XELJANZ® (tofacitinib)
Serious Infections: Patients treated with XELJANZ are at increased risk for developing serious infections leading to hospitalization or death, including active tuberculosis (TB), invasive fungal infections, bacterial, viral and other infections due to opportunistic pathogens. Avoid use of XELJANZ in patients with an active infection, including localized infections. If a serious infection develops, XELJANZ should be interrupted until the infection is controlled.

Malignancies and Lymphoproliferative Disorders: Consider the risks and benefits of XELJANZ treatment prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing XELJANZ in patients who develop a malignancy. Lymphoma, solid cancers, and NMSC have been reported in patients treated with XELJANZ. NMSC has been identified as an adverse drug reaction.

Laboratory Abnormalities: Lymphocytes, neutrophils, hemoglobin, and lipids should be monitored, as abnormalities in these parameters were associated with XELJANZ treatment in Phase 3 clinical trials. Please see the full Prescribing Information for more information.

Reporting Adverse Events
To report any adverse events with the use of XELJANZ, contact:
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- MedWatch (FDA safety information and adverse event reporting program) at 1-800-332-1088 or online at www.fda.gov/medwatch/report.htm

This is not a comprehensive representation of the potential risks associated with use of XELJANZ. For a complete description of these potential risks, please visit the XELJANZ

REMS web site (www.XELJANZREMS.com) for Prescribing Information and Medication Guide.

Appendix E: Journal Information Piece For Family Practitioners, General Practitioners, and Internal Medicine Specialists

Important Drug Warning for Family Practitioners, General Practitioners, and Internal Medicine Specialists about Risks and Potential Risks with XELJANZ

XELJANZ® (tofacitinib citrate) is an inhibitor of Janus kinases (JAKs) approved by the Food and Drug Administration (FDA) for adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). The recommended dose of XELJANZ is 5 mg twice daily.

The safety and efficacy of XELJANZ® for conditions other than RA have not yet been established.

Limitations of Use
XELJANZ is not recommended to be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.

Serious Risks of XELJANZ® (tofacitinib)
Serious Infections: Patients treated with XELJANZ are at increased risk for developing serious infections leading to hospitalization or death, including active tuberculosis (TB), invasive fungal infections, bacterial, viral and other infections due to opportunistic pathogens. Avoid use of XELJANZ in patients with an active infection, including localized infections. If a serious infection develops, XELJANZ should be interrupted until the infection is controlled.

Malignancies and Lymphoproliferative Disorders: Consider the risks and benefits of XELJANZ treatment prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing XELJANZ in patients who develop a malignancy. Lymphoma, solid cancers, and NMSC have been reported in patients treated with XELJANZ. NMSC has been identified as an adverse drug reaction.

Laboratory Abnormalities: Lymphocytes, neutrophils, hemoglobin, and lipids should be monitored, as abnormalities in these parameters were associated with XELJANZ treatment in Phase 3 clinical trials. Please see the full Prescribing Information for more information.

Reporting Adverse Events
To report any adverse events with the use of XELJANZ, contact:

- Pfizer Safety at 1-800-438-1985
- MedWatch (FDA safety information and adverse event reporting program) at 1-800-332-1088 or online at www.fda.gov/medwatch/report.htm

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Appendix F: Journal Information Piece For Emergency Medicine Specialists

Important Drug Warning for Emergency Medicine Specialists about Risks and Potential Risks with XELJANZ

XELJANZ® (tofacitinib citrate) is an inhibitor of Janus kinases (JAKs) approved by the Food and Drug Administration (FDA) for adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). The recommended dose of XELJANZ is 5 mg twice daily.

The safety and efficacy of XELJANZ® for conditions other than RA have not yet been established.

Limitations of Use
XELJANZ is not recommended to be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.

Serious Risks of XELJANZ® (tofacitinib)
Serious Infections: Patients treated with XELJANZ are at increased risk for developing serious infections leading to hospitalization or death, including active tuberculosis (TB), invasive fungal infections, bacterial, viral and other infections due to opportunistic pathogens. Avoid use of XELJANZ in patients with an active infection, including localized infections. If a serious infection develops, XELJANZ should be interrupted until the infection is controlled.

Malignancies and Lymphoproliferative Disorders: Consider the risks and benefits of XELJANZ treatment prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing XELJANZ in patients who develop a malignancy. Lymphoma, solid cancers, and NMSC have been reported in patients treated with XELJANZ. NMSC has been identified as an adverse drug reaction.

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Reporting Adverse Events
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Appendix G: Journal Information Piece For Pharmacists

Important Drug Warning for Pharmacists about Risks and Potential Risks with XELJANZ

XELJANZ® (tofacitinib citrate) is an inhibitor of Janus kinases (JAKs) approved by the Food and Drug Administration (FDA) for adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). The recommended dose of XELJANZ is 5 mg twice daily.

The safety and efficacy of XELJANZ® for conditions other than RA have not yet been established.

Limitations of Use
XELJANZ is not recommended to be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.

Serious Risks of XELJANZ® (tofacitinib)
Serious Infections: Patients treated with XELJANZ are at increased risk for developing serious infections leading to hospitalization or death, including active tuberculosis (TB), invasive fungal infections, bacterial, viral and other infections due to opportunistic pathogens. Avoid use of XELJANZ in patients with an active infection, including localized infections. If a serious infection develops, XELJANZ should be interrupted until the infection is controlled.

Malignancies and Lymphoproliferative Disorders: Consider the risks and benefits of XELJANZ treatment prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing XELJANZ in patients who develop a malignancy. Lymphoma, solid cancers, and NMSC have been reported in patients treated with XELJANZ. NMSC has been identified as an adverse drug reaction.

Laboratory Abnormalities: Lymphocytes, neutrophils, hemoglobin, and lipids should be monitored, as abnormalities in these parameters were associated with XELJANZ treatment in Phase 3 clinical trials. Please see the full Prescribing Information for more information.

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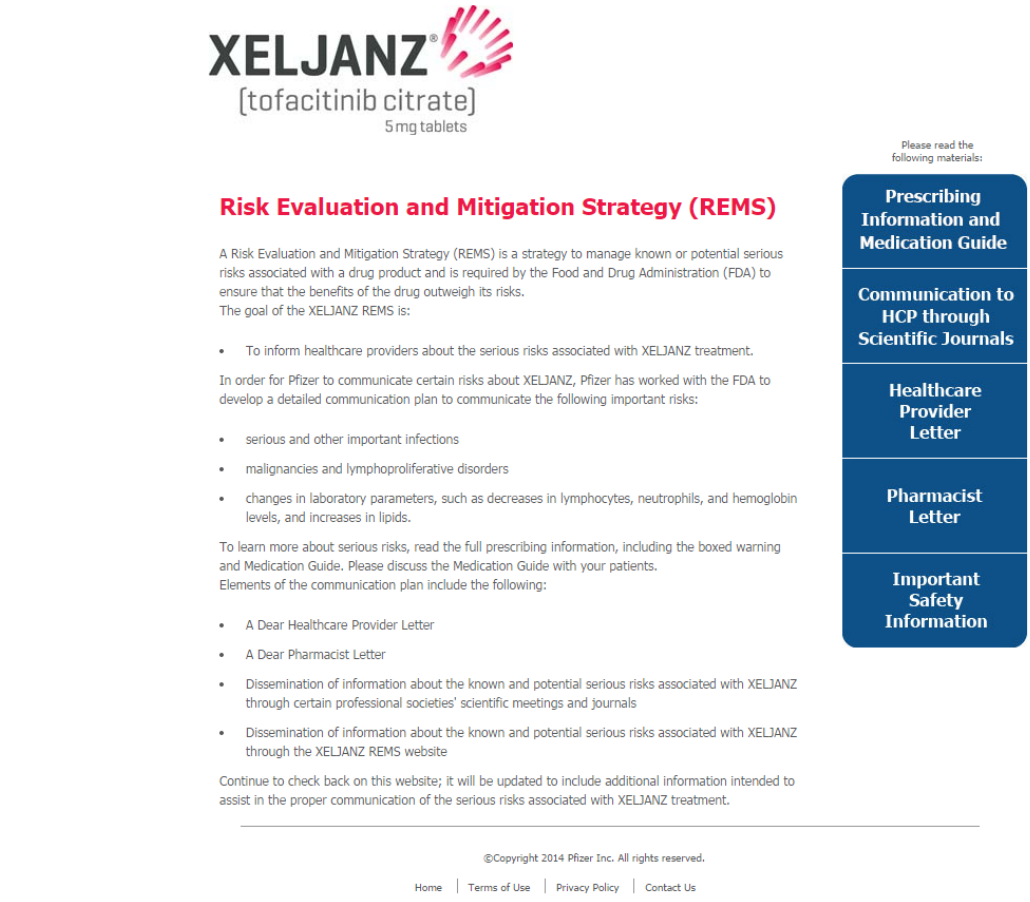
- Pfizer Safety at 1-800-438-1985
- MedWatch (FDA safety information and adverse event reporting program) at 1-800-332-1088 or online at www.fda.gov/medwatch/report.htm

This is not a comprehensive representation of the potential risks associated with use of XELJANZ. For a complete description of these potential risks, please visit the XELJANZ REMS web site (www.XELJANZREMS.com) for Prescribing Information and Medication Guide.

Appendix H: Screenshot of the Proposed REMS Website



This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CAROL F HILL
02/11/2015

SALLY M SEYMOUR
02/11/2015